

Centers for Disease Control and Prevention (CDC), 1600 Clifton Road, Mailstop E-03, Atlanta, GA 30333.

**SUPPLEMENTARY INFORMATION:** Consistent with OMB A-130 circular, Section 8.a.6.(j), Federal agencies are required to: "Provide adequate notice when initiating, substantially modifying, or terminating significant information dissemination products \* \* \*".

The Division of Quarantine's Travelers' Health Voice/Fax service is a major part of the CDC Voice/Fax Information Service. This service allows any caller access to the most current health related information by using a Touch-Tone telephone. The service has been in operation for 7 years, and in the most recent 12-month period received nearly 1 million telephone calls, providing automated voice-response information to those callers; it also provided 1.5 million pages of automated fax information. Information is provided in several levels of detail and complexity to reach a broad audience more effectively, including the general public and health-care professionals.

The Travelers' Health Voice/Fax service is undergoing major renovation. With the innovations in telecommunications technology and the wide availability of fax machines, the voice component of this service is much less effective. The necessarily lengthy text is difficult to listen to and capture all critical recommendations. Analysis of call flow indicated "caller hang-up" before the complete message was delivered. Receipt of hard-copy fax documents ensures that travelers and their health-care providers have accurate and comprehensive messages. The fax system also permits their careful review of the complex information. Therefore, the voice component of the Travelers' Health Voice/Fax service will terminate in December 1997. The revised service will provide international travelers and health-care providers a more efficient and user-friendly service. The Travelers' Health Information will be available by fax through a toll-free call. In addition, the same information will be on the Internet on the CDC web site at: <http://www.cdc.gov> (select Travelers' Health).

Dated: January 7, 1998.

**Joseph R. Carter,**

*Acting Associate Director for Management and Operations, Centers for Disease Control and Prevention (CDC).*

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## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### Centers for Disease Control and Prevention

#### Fees for Consultation Services for Ship Construction and Renovation

**AGENCY:** Centers for Disease Control and Prevention (CDC), Department of Health and Human Services (DHHS).

**ACTION:** Extension of request for comments.

A notice requesting comments from all interested parties concerning an additional vessel size category for ships >90,000 gross register tonnage and charging fees for consultation services for ship construction and renovation was published in the **Federal Register** on November 17, 1997 (Volume 62, Number 221).

*This notice is amended as follows:* On page 61336, third column, under the heading **DATES**, the date for submitting written comments to this notice has been extended from January 2, 1998, to January 30, 1998.

All other information and requirements of the November 17, 1997, **Federal Register** notice remain the same.

Dated: January 7, 1998.

**Joseph R. Carter,**

*Acting Associate Director for Management and Operations, Centers for Disease Control and Prevention (CDC).*

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## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### Food and Drug Administration

[Docket No. 97P-0441]

#### Administrative Proceeding; Re: Pharmanex, Inc.

**AGENCY:** Food and Drug Administration, HHS.

**ACTION:** Notice of opportunity to comment.

**SUMMARY:** The Food and Drug Administration (FDA) is announcing that comments related to the regulatory status of Cholestol<sup>TM</sup> may be submitted until January 30, 1998. This action is being taken as a part of the agency's deliberation on the regulatory status of Cholestol<sup>TM</sup>. All comments postmarked on or before January 30, 1998, will be accepted as part of the official record for this matter.

**DATES:** Submit written comments by January 30, 1998.

**ADDRESSES:** Submit written comments regarding this issue to the Dockets Management Branch (HFA-305), Food and Drug Administration, 12420 Parklawn Dr., rm. 1-23, Rockville, MD 20857, ATTN: Docket 97P-0441.

**FOR FURTHER INFORMATION CONTACT:** Ilisa B.G. Bernstein, Office of Policy (HF-23), Office of the Commissioner, Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301-827-3380, or [IBernste@oc.fda.gov](mailto:IBernste@oc.fda.gov).

**SUPPLEMENTARY INFORMATION:** On October 29, 1997, FDA received a document entitled "Petition to the Food and Drug Administration for a Stay of Action With Respect to Cholestol<sup>TM</sup> Dietary Supplement," (petition) from Pharmanex, Inc. (Pharmanex). The petition requested FDA to stay the effect of a September 30, 1997, FDA letter to Pharmanex discussing the regulatory status of Cholestol<sup>TM</sup>, and to also stay any form of enforcement action adverse to Pharmanex or Cholestol<sup>TM</sup>. In response to the petition, in a letter dated November 14, 1997, from William Schultz, FDA's Deputy Commissioner for Policy, to Stuart Pape, Counsel to Pharmanex, Inc., the agency informed the petitioner that it was not acting on the petition because there was no administrative action taken by the Commissioner of Food and Drugs capable of being stayed, and because FDA decisions to take enforcement actions are not subject to petitions or other action by interested persons outside the agency. In the November 14, 1997 letter, the agency also informed the petitioner that it was initiating an administrative proceeding under 21 CFR 10.25(b) to decide the regulatory status of Cholestol<sup>TM</sup>. The agency stated that it would use its "best efforts" to conclude the proceeding by the end of 1997.

Since the November 14, 1997, letter was issued, FDA has received a number of comments regarding the regulatory status of Cholestol<sup>TM</sup>, including three additional submissions from Pharmanex (one received by the agency on December 29, 1997). Several requests for extensions of time to submit comments have also been received. Under the circumstances, it is apparent that additional time is required to afford all interested parties adequate opportunity to submit comments in this matter.

With this notice the agency announces that comments related to this matter may be submitted until January 30, 1998. All comments postmarked on or before January 30, 1998, will be accepted as part of the official record for this matter. Comments should be sent to the Dockets Management Branch (address above) and should be identified